UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

Subject: Azinphos-methyl: EFED's Data Requests, Risk Characterization, and Risk Reduction Options

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This memo was written in response to questions raised by SRRD to EFED in September 2001. EFED's risk assessment for the RED was completed in July 1999. In the interim the understanding of certain aspects of azinphos-methyl risk has changed (most notably the level of concern for drinking water). This memo basically provides SRRD with an update of azinphos-methyl requirements, risks, and risk reduction measures in the period since EFED's RED chapter was completed.

Data Requirements.
The following data have been requested by EFED to continue to support the azinphos-methyl registration:

- Aerobic soil metabolism data. The aerobic soil metabolism guideline (162-1) has been fulfilled. However, only a single study is available. When only a single study is available, the half-life is multiplied by three in order to account for uncertainty in the estimate. The addition of two or more aerobic soil metabolism studies on a variety of soils would substantially improve the quality of the estimated environmental concentrations in water, and most likely reduce their values.

- Aquatic persistence data. The aerobic aquatic metabolism study (162-4) is not normally a data requirement for pesticides with uses such as azinphos-methyl. However, the addition of this data would substantially improve the quality of the modeling estimates. The current estimate of persistence in aquatic environments is based on an extrapolation from a single aerobic soil metabolism study and there is substantial uncertainty in this estimate. The availability of guideline aerobic aquatic metabolism data would could be used to refine drinking water and aquatic ecological exposure assessments.

- Field dissipation data. The field dissipation studies from California (MRID#426479-01) were not acceptable and while the submitted studies did provide some supporting data, this data requirement is not yet fulfilled. In addition, no field dissipation studies have been conducted in the southeastern U.S. EFED recommends that three field dissipation studies be conducted, two for the west coast, one each in California and Washington and the other in the southeast (peach orchards).

- Standard fish toxicity data. Two fish toxicity studies may be upgraded with the submission of additional data: Freshwater fish early life stage study (MRID# 405796-01) - this study may be upgraded to core and the guideline requirement fulfilled by submitting the raw water quality data, fish growth data, and offspring for the control group. Estuarine fish life cycle test study (MRID # 420216-01) - this study may be upgraded to core and the guideline requirement fulfilled by submitting the raw water quality data, fish growth data, and offspring for the control group.

- Additional fish toxicity data. The Agency has particular concern for the potential chronic effects for threatened and endangered salmonids in the Pacific Northwest. (see D256900, Review of "Historical Occurrence of Acephate, Azinphos-methyl, Chlorpyrifos, Diazinon, and Malathion in Waters of the United States 1990-1997") Because the chronic NOAEL is exceeded by chronic estimates in some water bodies in this region, EFED believes the fish early life stage and fish full life cycle studies should be conducted for the following fish species, Chinook salmon (*Onchorynchus tshawytscha*), coho salmon (*O. kisutch)*, and sockeye salmon (*Onchorynchus nerka*). These tests should be performed on strains of these species which are not endangered or threatened.

EFED previously indicated that water monitoring studies could be useful in some circumstances to support drinking water risk assessment, and also to assess ecological risks. DWLOCs are close to Tier 2 EEC's for typical rates which are similar to proposed application rates. In order to significantly refine drinking water risks EFED requires additional data on azinphos-methyl persistence in aquatic environments. This data would likely preclude the necessity of drinking water monitoring data. Although additional drinking water monitoring data could also be useful in ecological risk assessment, EFED believe sufficient monitoring data exists to adequately characterize ecological risks. EFED have consulted with Larry Turner in the Endangered

Species Program of OPP and he has indicated that there is not currently a need for additional monitoring data to support endangered species programs on the Pacific Coast. Consequently, we are not currently recommending that water monitoring studies be conducted to support the continuing azinphos-methyl registrations.

Data reviewed since the 1999 technical briefing.
The Agency received a number of documents which were submitted to be additional data for consideration by the Program. The most prominent of these was a review of historical monitoring data *"Historical Occurrence of Acephate, Azinphos-methyl, Chlorpyrifos, Diazinon, and Malathion in Waters of the United States 1990-1997"* submitted by the primary registrant, Bayer. The review of this document (D256900) found that the vast majority of the data for azinphos-methyl had been already considered in the RED. Of the data that had not been previously reviewed, most was conducted in places where there was minimal or unknown usage of azinphos-methyl. The registrant did not provide any ancillary data to support the review or interpretation of the data. In these cases, the Program obtained the original studies and these were reviewed directly. Of particular concern was the occurrences in the state of Washington. Thirteen of the 34 sites sampled had detects, eight sites had detections over 0.1 µg L^{-1}, and ten out of 14 sites that had more than five samples taken had detections. One site in Pacific County, probably associated with cranberries had 100% detections in 26 samples. Other studies in Mississippi Valley and Arkansas did not have detections, but the amount of azinphos-methyl used above the sampling sites was not known although crops which have uses, particularly cotton were grown in at least some of the basins in the Arkansas site.

Analytical method for Water and Independent Laboratory Validation
An analytical metyhod for azinphos-methyl was submitted for review and was sent to Bay Saint Louis laboratory for confirmation. However, the method did not include an Independent Laboratory Validation (ILV) which is required prior to review. The analytical method review process (including the ILV) is necessary to provide assurance that monitoring data is of an acceptable quality for regulatory and legal purposes. Although drinking water monitoring is not being requested at this time there are other reasons that the analytical method for azinphos-methyl in should be validated. The ability of azinphos-methyl to reach surface water and kill aquatic organisms is documented in monitoring and incident data. Given the number of aquatic incidents associated with azinphos-methyl and its high aquatic toxicity, a well validated analytical method for water should be available for state, regional, and tribal agencies for enforcement purposes. For investigation and litigation of aquatic incidents related to azinphos-methyl the water method should be well accepted. Thus EFED recommends that an ILV for azinphos-methyl in water should be submitted.

Incidents update
Although azinphos-methyl has more aquatic incidents in our incident data base than any other pesticide, no major incidents associated with normal azinphos-methyl use were reported in the year 2000. Minor incidents may have been reported in aggregate reports with other pesticides but not enough time was available to determine the extent of these potential occurrences. Major incidents are reported by the registrant in individual reports. Minor incidents are reported in

aggregate with other pesticides. EFED is not aware of other criteria distinguishing major from minor incidents (e.g. the number of fish killed).

Azinphos-methyl has 143 incidents reported prior to 2000, only including incidents that are probable or highly probable to have associations with the azinphos-methyl and excluding those associated with misuse. This number of incidents is more than twice the number of incidents of the next highest chemical, which is chlorpyrifos with 63 incidents. Azinphos-methyl is responsible for over 21% of all aquatic incidents. A large majority of the incidents are associated with the cotton and sugar cane uses. Seventy seven of these incidents are associated with cotton and 37 were associated with sugar cane. In addition, there are 15 incidents that are unclassifed or classifed as “agricultural” that in Louisiana that highly likely to have been associated with one of these two use patterns. This accounts for 129 of the 143 incidents. Of the remainder, 1 is associated with apples (MO), 1 with citrus (FL), 3 with potatoes (ME), and 1 with peaches (MO). There are also 7 incidents that unclassifed or classifed as “orchard” in New York (2), Washington (1), Wisconsin (1), North Carolina (1), Maine (1), and Michigan (1). If all events associated with azinphos-methyl are included, which adds misuses, and those with less certainty, there are 256 incidents. These include an almond incident (CA), one more apple (NC), 1 blueberry (ME), 1 forestry (AR), and one “nursery” (GA). The balance are associate with sugar cane and cotton.

Aside from the number of incidents, the size of the incidents and kinds of species killed for azinphos-methyl stand in contrast to other currently registered pesticides.   Some of the incidents associate with sugar cane are listed as “6 miles long” and “2 miles long”. Ten others have over 10,000 fish killed. Some of the fish included are those not otherwise found in the incident database including, gar, catfish, buffalo, and bowfin, and carp. These “aquatic incidents” also included some otherwise terrestrial or semiaquatic species including turtles, an alligator, a dog, and a pig.

In addition to the aquatic incidents, there were 12 terrestrial incidents. Two of these were concurrent with an aquatic incident. Of these 12, five were misuses. In contrast, phosmet, the primary alternative to azinphos-methyl had 4 terrestrial incidents and 1 aquatic incident. All the terrestrial incidents were bees. There is little additional information on the aquatic incident other than it occurred in North Carolina from use on an orchard.

Risk Quotient Assessment
Based on Tier 2 surface water modeling using PRZM and EXAMS with pond scenarios, *all uses exceed the level of concern for fish and invertebrates for typical and maximum application patterns.*   In addition, the level of concern for chronic risk in aquatic environments was exceeded for every use at the maximum application rate and for every use except for apples in the western United States with the typical application practice.

The toxicity of azinphos-methyl to a wide variety of fish has been measured including salmonids, minnows, and perch. The most sensitive species in a core study was the brook trout with an LC_{50} at 1.2 µg L^{-1} (ppb). However, all salmonids had an LC_{50} less than 10 µg L^{-1}. Catfish appeared to be the least sensitive with LC_{50}’s greater than 1 mg L^{-1}(ppm). Of 16 species tested 9 had LC_{50}'s of less than 10 µg L^{-1}, indicating that many species are susceptible to azinphos-methyl near the level of the most sensitive species. For crops that are still registered, the maximum label application practice produces 1 in 10 year EEC's above 10 µg L^{-1} for apples, walnuts, potatoes, cherries, and peaches. This is consistent with the number and magnitude of the aquatic incidents that have occurred from azinphos-methyl use.

The Tier 2 ecological assessment is done using a pond, but the assessment is meant to protect a variety of vulnerable water body types that occur near the top of watersheds. These include, first-order streams, ponds, wetlands, prairie pothole, playa lakes. Some of these water bodies are more vulnerable than the standard pond. If the level of concern is exceeded in the Tier 2 assessment, it is likely that impacts in the environment at the upper reaches of some watersheds will occur some of the time. Tier 2 EEC's represent a relatively rare event, one that is expected to recur only once every 10 years at the modeled site. The extent of impact in the watershed, that is, how far down stream from the use sites impacts are expected, cannot be determined using this assessment. This would require a basin scale modeling, a capability not currently available for assessment of pesticides.

Previous mitigation measures
Following the massive fish kills in Louisiana in 1991 and 1992, the number of applications per year allowed on the label was reduced but more significantly, the state of Louisiana implemented a prescription use program which required explicit permission from the state to use the pesticide. Despite these label changes and requirements, 4 more incidents occurred in 1994 and 1995.

In 1999 the cotton use east of the Mississippi River was phased out, as well as all the sugar cane use. *This substantially mitigated the worst ecological risks identified for azinphos-methyl.* However, the ecological risks for other uses are still substantial. The thirteen incidents associated with other remaining crops would rank azinphos-methyl ninth in total number of incidents among pesticides that have current registrations.

Summary of proposed mitigation measures
Some risk reduction options which have been considered for azinphos-methyl are listed below with comments to their effectiveness.

> *Cancel, phase-out, time-limited:* These options would eventually eliminate the ecological risk from azinphos-methyl. Alternatives to azinphos-methyl are all expected to have substantially lower aquatic risk. Phosmet is expected to have approximately equal avian risk.
>
> *Increased re-entry interval:* Changes to re-intery intervals have been implemented and have already substantially mitigated the aquatic risk in peaches, however, changes in management practices could result in increased azinphos-methyl usage at a later date. For more permanent mitigation, adjustment of reintry interval should be combined with label rate reductions.

Decreasing number of applications: This decreases acute risk in proportion to number of uses removed. It can substantially mitigate chronic risk, however chronic risk is poorly define at this time due to lack of toxicological and fate data.

Cancel aerial application: The prohibition of aerial applications of azinphos-methyl would be expected to greatly reduce drift, non-target exposure (including aquatic), and the associated risk.

Spray drift label language: The spray drift label language in the draft Spray and Dust Drift PR Notice would improve the Guthion labels to provide clear and enforceable directions on managing drift. The draft PR Notice (http://www.epa.gov/opppmsd1/PR_Notices/prdraft-spraydrift801.htm) specifies that the droplet spectrum to be applied should be defined on product labels along with a proposed format for no-spray zones (buffer zones).

Airblast Application Restrictions: Risks from drift from airblast applications may be further reduced by limiting the spraying of outside rows. By only spraying the outer side of outer orchard rows (rows on the edge of an orchard), drift from spray passing through the canopy is reduced.

No-spray zones: No-spray buffers around permanent water bodies are recommended for mitigation of spray drift. The inclusion of an unsprayed area between application sites and sensitive areas allows for spray drift to dissipate prior to depositing. In some instance, no-spray zones may also be effective at reducing azinphos-methyl runoff.

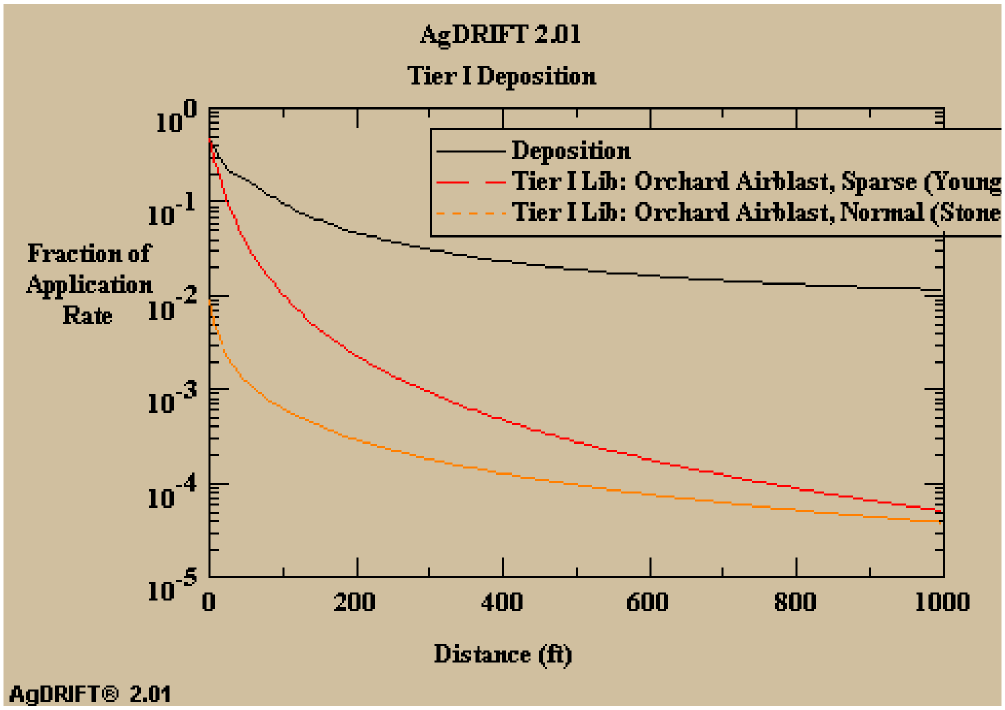
Vegetated buffer strips to reduce runoff: Properly maintained vegetated buffer strips can reduce pesticide runoff to adjacent water bodies. OPP and USDA has published guidance on developing and maintaining vegetated buffer strips (Conservation Buffers to Reduce Pesticide Losses, March 2000). Vegetated buffer strips can reduce pesticide runoff by reducing sheet and channelized runoff from the application area and reducing the erosion of contaminated soil. The effectiveness of vegetated buffer strips is highly dependent on a number of factors which will vary from site to site. In general, the effectiveness of buffer strips in reducing surface water contamination is lower in areas with higher rainfall, irregular topography, or slopes greater than 8%. It is unlikely that a buffer strip of less than 50 ft will be effective at significantly reducing runoff levels. The complex interaction of a number of factors makes it difficult to quantify the effectiveness of vegetated buffer strips in a general sense. Also the need for intensive involvement of the land owner/manager in engineering, cultivating, and managing the strips makes it difficult rely on vegetated buffer strips as a label mitigation options.

Prohibit dormant use: Dormant applications have the potential to result in relatively high off-target deposition due to spray drift. The lack of foliage in dormant orchard allows more air movement which can carry fine spray outside the target area. It may be possible to mitigate the aquatic risk with buffer strips.

Quantitative analysis of spray drift risk
Aerial applications tend to result in the highest off-target drift levels. Applications to young and dormant orchards can also result in drift levels expected to exceed levels of concern for fish and aquatic invertebrate at large downwind distances. The spray drift deposition model AgDRIFT (version 2.01) was used to estimate exposure to aquatic organisms resulting from different application methods with varying distance.

Spray drift is the movement of spray droplets off-target during or shortly after application. Spray drift deposition is typically highest near application sites and decreases with distance. Higher deposition into water bodies leads to higher aquatic exposures. A Guthion 2L label (updated 3/1/00) was reviewed to determine application limitations which may affect spray drift deposition levels. No mandatory restrictions were found related to droplet size (a critical parameter in drift of aerial and ground boom applications). Application conditions are consistent with those available in Tier 1 AgDRIFT. Spray drift deposition curves from Tier 1 AgDRIFT are presented below for aerial and orchard airblast applications.

Figure 1. Downwind deposition levels with distance resulting from aerial application (top curve), airblast applications to dormant or young orchards (middle curve), and airblast applications to mature apple orchards (bottom curve) from AgDRIFT 2.01.



The curves in Figure 1 provide reasonable estimates of deposition at given distances from treated areas. Using toxicity data from studies conducted on fish and the dimensions of the standard pond used in EFED risk assessment it is possible to estimate no-spray zone distances that would generally reduce risks to fish to acceptable levels (Table 1).

Table 1. Dissipation distances required for spray drift deposition from aerial and orchard airblast applications to be reduced below levels of concern for fish.

Azinphos-methyl Application Rate (lbs a.i. /acre)	Aquatic Concentration Level of Concern for Fish	No Spray Zone / Dissipation Distance (ft)		
		Aerial Applications[1]	Orchard Airblast Applications[2]	
			Young/Dormant Orchards	Mature/Foliated Apples
0.1	0.6 µg/L (0.5 x brook trout LC_{50})	15	5	0
0.5		350	60	0
0.75		620	75	0
1		>1000	90	0
1.5		>1000	120	0
2		>>1000	150	0
3		>>>1000	190	0

Dissipation distances expected to reduce risks to acceptable levels for fish were generally largest for aerial applications. Applications to young or sparsely foliated orchards resulted in higher deposition levels and larger dissipation distances than applications to mature foliated apple orchards. Based on available data (Spray Drift Task Force reports on orchard airblast drift MRID 439257-01), foliated apple canopies tend to be one of the most efficient at capturing spray and reducing off-target deposition.

The calculated dissipation distances in Table 1 are based on toxicity data for fish in a substantial

[1]Aerial spray drift modeling was consistent with applications conducted under relatively high drift conditions but not at the highest levels allowed under the label. The spray quality (droplet size) used in modeling was a medium/fine spray which is commonly used for insecticide applications in general. Using a finer spray is not prohibited on the label and would be prone to result in higher deposition levels.

[2]Orchard airblast drift modeling is limited to more median drift conditions and applying "Best Management Practices" which are not mandatory on the Guthion label. Orchard airblast deposition levels were multiplied by 3 to be closer to 90th percentile deposition values (see EFED's SAP report on tolerance bounds for drift deposition from orchards: http://www.epa.gov/scipoly/sap/1999/july/airblast.pdf) and compare better with conditions used for aerial applications.

pond (1 hectare and six feet deep). The assessment assumes that spray drift deposition is mixed evenly through the water body. In actuality, after a drift event, concentrations would vary through the water body. Higher concentrations would be expected to occur near the surface and in shallow areas closer to the application site and lower concentrations in other areas. Smaller and shallower water bodies than the standard pond would have proportionally higher concentrations of azinphos-methyl since depositing spray drift would be less diluted. Also, larger no-spray zones would be necessary to reduce deposition to below levels of concern for aquatic invertebrates that are more sensitive to azinphos-methyl than fish.